APPENDIX A
INDEPENDENT REVIEW ORGANIZATION

This Appendix contains the requirements relating to the Independent Review Organization (IRO) required by Section III.D of the CIA.

A. IRO Engagement.

Purdue shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and/or objective fashion, as set forth in Paragraph D. Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG will notify Purdue if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Purdue may continue to engage the IRO.

If Purdue engages a new IRO during the term of the CIA, this IRO shall also meet the requirements of this Appendix. If a new IRO is engaged, Purdue shall submit the information identified in Section V.A.8 to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG will notify Purdue if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Purdue may continue to engage the IRO.

B. IRO Qualifications.

The IRO shall:

1. assign individuals to conduct the Promotional and Product Services Engagement who have expertise in the Federal health care program and FDA requirements applicable to sales, marketing, research, and promotion of pharmaceutical products. The assigned individuals shall also be knowledgeable about the general requirements of the Federal health care program(s) under which Purdue products are reimbursed;

2. assign individuals to design and select the Promotional and Product Services Engagement samples who are knowledgeable about the appropriate statistical sampling techniques; and

3. have sufficient staff and resources to conduct the reviews required by the CIA on a timely basis.

C. IRO Responsibilities.

The IRO shall:

1. perform each Promotional and Product Services Engagement in accordance with the specific requirements of the CIA, including Appendix B to the CIA;

2. follow all applicable Federal health care program and FDA requirements in making assessments in Promotional and Product Services Engagement;

3. respond to all OIG inquires in a prompt, objective, and factual manner; and

5. prepare timely, clear, well-written reports that include all the information required by Appendix B.

D. IRO Independence/Objectivity.

The IRO must perform the Promotional and Product Services Engagement in a professionally independent and/or objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or engagements that may exist between the IRO and Purdue.

E. IRO Removal/Termination.

1. *Provider.* If Purdue terminates its IRO during the course of the engagement, Purdue must submit a notice explaining its reasons to OIG no later than 30 days after termination. Purdue must engage a new IRO in accordance with Paragraph A of this Appendix.

2. *OIG Removal of IRO.* In the event OIG has reason to believe that the IRO does not possess the qualifications described in Paragraph B, is not independent and/or objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, OIG may, at its sole discretion, require Purdue to engage a new IRO in accordance with Paragraph A of this Appendix.

Prior to requiring Purdue to engage a new IRO, OIG shall notify Purdue of its intent to do so and provide a written explanation of why OIG believes such a step is necessary. To resolve any concerns raised by OIG, Purdue may request a meeting with OIG to discuss any aspect of the IRO's qualifications, independence or performance of its responsibilities and to present additional information regarding these matters. Purdue shall provide any additional information as may be requested by OIG under this Paragraph in an expedited manner. OIG will attempt in good faith to resolve any

differences regarding the IRO with Purdue prior to requiring Purdue to terminate the IRO. However, the final determination as to whether or not to require Purdue to engage a new IRO shall be made at the sole discretion of OIG.

Appendix B to CIA for Purdue Pharma L.P.
Promotional and Product Services Engagement

I. IRO Engagement, General Description

As specified more fully below, Purdue shall retain an Independent Review Organization(s) (IRO) to perform engagements to assist Purdue in assessing and evaluating certain of its systems, processes, policies, and procedures related to Product Services Related Functions as defined in Section II.C.2 of the CIA (Promotional and Product Services Engagement). The Promotional and Product Services Engagement shall consist of two components - a systems review (the Promotional and Product Services Systems Review) and a transactions review (the Promotional and Product Services Transactions Review), as described more fully below. Purdue may engage, at its discretion, a single entity to perform both components of the Promotional and Product Services Engagement, provided that the entity has the necessary expertise and capabilities to perform both.

The Promotional and Product Services Systems Review shall be a review of Purdue's systems, processes, policies, and procedures (including the controls on those systems, processes, policies, and procedures) relating to Product Services Related Functions as set forth in Section II.A below. If there are no material changes in Purdue's applicable systems, processes, policies, and procedures during the term of the CIA, the IRO shall perform the Promotional and Product Services Systems Review for the second and fourth Reporting Periods. If Purdue materially changes its systems, processes, policies, and procedures relating to Product Services Related Functions (other than any such material changes that occur during the second and fourth Reporting Periods), the IRO shall perform an additional Promotional and Product Services Systems Review covering the Reporting Period in which such changes were made in addition to conducting the Review for the second and fourth Reporting Periods. The additional Systems Review(s) shall consist of: 1) an identification of the material changes; 2) an assessment of whether other systems, processes, policies, and practices previously reported did not materially change; and 3) a review of any systems, processes, policies, and practices that materially changed.

The Promotional and Product Services Transactions Review shall include reviews of a sample of Inquiries reflected in the Product Inquiries Database relating to the Covered Product(s) and a sample of the Promotion Monitoring Program Forms relating to the Covered Product(s) as set forth in Section III.A below. The IRO shall perform the Promotional and Product Services Transactions Review on an annual basis and, except for the Transactions Review for the first Reporting Period, each IRO review shall cover a single complete Reporting Period. As of the Effective Date of this CIA, Purdue represents that it is in the process of modifying certain systems, processes, and policies

associated with the Product Inquiries Database and with the Promotion Monitoring Program. Purdue further represents that these modifications will be substantially completed by the end of the second quarter of the first Reporting Period. Therefore, for the first Transactions Review only, the Review shall cover the last two quarters of the first Reporting Period rather than covering the complete Reporting Period. Thereafter, each subsequent Transactions Review shall cover a complete Reporting Period.

II. Promotional and Product Services Systems Review

A. General Business Policies and Practices for Review

For at least the second and fourth Reporting Periods, the IRO shall review Purdue's systems, processes, policies, and procedures associated with the following activities, systems, and policies (Reviewed Policies and Practices):

1) Purdue's systems, policies, processes, and procedures applicable to the development of Materials (as defined in Section II.C.3 of the CIA), the Materials Review process, and the process by which Materials are discontinued from use and notification of the discontinuation is provided to all applicable personnel, including sales representatives and marketing personnel;

2) Purdue's systems, policies, processes, and procedures applicable to the manner in which Purdue sales representatives respond to requests or inquiries relating to information about non-FDA approved uses (*e.g.* off-label uses) of Purdue's products. This review shall include the manner in which sales representatives refer such requests and inquiries to Medical Services;

3) Purdue's systems, policies, processes, and procedures applicable to the manner in which Purdue sales representatives provide Materials, including Materials concerning FDA approved product label information regarding withdrawal, drug tolerance, drug addiction, or drug abuse of Purdue's products or respond to requests from HCPs for information about Purdue's products;

4) Purdue's systems, policies, processes, and procedures applicable to the manner in which Medical Services and Medical Liaisons provide information about Purdue's products concerning any off-label uses of the products or other product-related information, including, but not limited to, information related to withdrawal, drug tolerance, drug addiction, or drug abuse of Purdue's products. This review shall include a review of:

a. the form and content of information and, if applicable, Materials, disseminated by Medical Services and Medical Liaisons in response to Inquiries and the means by which Purdue tracks and records what information or, if applicable, Materials are provided to HCPs;
b. Purdue's internal review and development process for the information disseminated by Medical Services and Medical Liaisons in response to inquiries for information about Purdue products;
c. Purdue's systems, processes, and procedures to track Medical Services information and/or Materials, as applicable, requests and responses to such requests;
d. the manner in which Medical Services and Medical Liaisons, as applicable, collect and document information in the Product Inquiries Database;
e. the process through which Medical Services produces the Product Inquiries Reports provided to the Corporate Compliance Department; and
f. the internal review of Product Inquiry Reports and related processes, procedures, and the resolution of any issues identified;

5) Purdue's policies and procedures applicable to the manner and circumstances in which Medical Services personnel and Medical Liaisons participate in promotional activities with HCPs (either alone or with members of the sales force) and the role of the Medical Services personnel and Medical Liaisons in such activities;

6) Purdue's systems, policies, and procedures relating to funding or sponsorship of any Non-Promotional Educational Activity or Informational Activity. This review shall include a review of the following items, as applicable:

a. the processes and procedures used to approve the funding (including justification of the amount thereof) or sponsorship of the Non-Promotional Educational Activity or Informational Activity;
b. whether and in what manner Purdue tracks or monitors the prescribing habits of the use of Purdue products by individuals or entities receiving the funding or sponsorship of the Non-Promotional Educational Activity or Informational Activity, if any; and
c. the budget funding source within Purdue (*e.g.*, department or division) from which funds are allocated for the Non-Promotional Educational Activity or Informational Activity.

In addition, with respect to Non-Promotional Educational Activities, this review shall include a review of the following items:

d. the criteria used to determine whether and under what circumstances the funding or sponsorship of the Non-Promotional Educational Activity would be provided;
e. the processes and criteria used to select recipients of the funding or sponsorships of the Non-Promotional Educational Activity, including the role played by sales representatives in the processes (if any), and the circumstances under which there may be exceptions to the processes;

f. Purdue's Policies and Procedures related to circumstances under which the recipient or the recipient's agent is required to disclose Purdue's funding or sponsorship of the Non-Promotional Educational Activity and any financial relationship Purdue may have with the recipients; and

g. Purdue's Policies and Procedures relating to the independence of any of the Non-Promotional Educational Activity programs funded;

Further, with respect to Informational Activities, this review shall include a review of the following items:

h. Purdue's Policies and Procedures relating to the content and promotional nature of any Informational Activity programs sponsored by Purdue;

7) Purdue's systems, policies, and procedures relating to its Promotion Monitoring Program. This review shall include a review of the following items:

a. the processes and procedures used in connection with the Promotion Monitoring Program;
b. the frequency and duration of monitoring activities under the Promotion Monitoring Program;
c. the identification of Purdue personnel responsible for the monitoring of activities in connection with the Promotion Monitoring Program and their role with regard to the Program; and
d. the performance criteria against which the sales representatives are evaluated in connection with the Promotion Monitoring Program;

8) Purdue's policies, processes, and procedures relating to the disciplinary actions that Purdue may impose in the event a Covered Person violates a Purdue policy or procedure; and

9) Purdue's systems, policies, processes, and procedures for compensating (including with salaries and bonuses) Relevant Covered Persons engaged in promoting or

selling Purdue products. This shall include a review of the bases upon which compensation is determined and the extent to which compensation is based on product performance.

B. Promotional and Product Services Review Report

The IRO shall prepare a report based upon each of its Systems Reviews. For each of the Reviewed Policies and Practices identified in Section II.A above, the report shall include the following items:

1) a description of the documentation (including Policies and Procedures) reviewed and any personnel interviewed;

2) a detailed description of Purdue's systems, policies, processes, and practices with regard to the items identified in Sections II.A.1-9 above, including a general description of Purdue's control and accountability systems (*e.g.*, documentation and approval requirements, tracking mechanisms, *etc.*) and written Policies and Procedures relating to the Reviewed Policies and Practices;

3) a description of the manner in which the control and accountability systems and the written policies relating to the items identified in Sections II.A.1-9 above are made known or disseminated within Purdue;

4) a detailed description of any system used to track and respond to Inquiries about Purdue's products that are handled by Medical Services;

5) a description of Purdue's systems, policies, and procedures used to track the review and approval of Materials relating to Purdue products through the Materials Review process, the systems, policies, and procedures used to disseminate approved Materials to sales or marketing personnel, and the systems, policies and procedures to implement the discontinuation of use of any Materials;

6) a general description of the disciplinary measures that Purdue has established for failure to comply with its systems, processes, policies and procedures relating to the Reviewed Policies and Practices;

7) a detailed description of Purdue's compensation system (including salaries and bonuses) for Relevant Covered Persons engaged in the promotion and sales of Purdue products, including a description of the bases upon which compensation is determined and the extent to which compensation is based

on product performance. To the extent that Purdue may establish compensation differently for individual products, the IRO shall report separately on each type of compensation arrangement;

8) findings and supporting rationale regarding any weaknesses in the systems, processes, policies, and practices associated with the Reviewed Policies and Practices, if any; and

9) recommendations to improve any of the systems, policies, processes, or practices associated with the Reviewed Policies and Practices, if any.

III. Promotional and Product Services Transactions Review

The IRO shall conduct a Promotional and Product Services Transactions Review for each of the Reporting Periods. As described below, the Transactions Review shall include reviews of a sample of Inquiries reflected in the Medical Services Product Inquiries Database (or "Database") and a sample of the Promotion Monitoring Program Forms resulting from the Promotion Monitoring Program.

A. Promotional and Product Services Transactions Review

1. *Review of Sales Force Related Inquiries Made to Medical Services.*

As set forth in Section III.B.2 of the CIA, Purdue has established Policies and Procedures that address the process by which and standards according to which Medical Services personnel and Medical Liaisons respond to Inquiries from HCPs about Purdue products.

a. *Internal Review of Product Inquiry Database.*

Purdue shall document and record all Inquiries received by Medical Services in the Product Inquiries Database. The information to be included in the Product Inquiries database is set forth in Section III.B.2.e. Medical Services assigns each inquiry into Categories and Topics. Section III.J.1 of the CIA defines Focus Inquiries. All Inquiries that are generated by or in connection with an interaction between a sales representative and an HCP (*e.g.*, through a call made by a sales representative from an HCP's office, through a Medical Information Request Form, or through an Inquiry in which the HCP identifies the sales representative involved) shall be known as "Sales Force Related Inquiries." For purposes of each Reporting Period, the OIG shall identify the Categories and Topics of Sales Force Related Inquiries that shall constitute the Focus Inquiries for the period.

As set forth in Section III.J of the CIA, Purdue undertakes several internal steps with regard to Focus Inquiries. The Corporate Compliance Officer reviews a sample of the Focus Inquiries referenced in Focus Inquiry Reports on a semi-annual basis. The Compliance Officer identifies those Focus Inquiries relating to situations in which improper promotion of the Purdue products may have occurred. Focus Inquiries for which the Compliance Officer determines that improper promotion may have occurred shall be known as "Suspect Inquiries." Additional Compliance Reviews are conducted for Suspect Inquiries, and the requirements of the Additional Compliance Reviews are set forth in Section III.J.2.b.

b. *IRO Review of Focus Inquiries.*

As part of the Promotional and Product Services Transactions Review, the IRO shall evaluate Purdue's processes relating to its Product Inquiries Database, the assignment of the Inquiries into Categories and Topics, and Additional Compliance Reviews. Specifically, for each Reporting Period, the IRO shall select a random sample of 15 Sales Force Related non-Focus Inquiries relating to the Covered Product(s), and a random sample of 60 Focus Inquiries relating to the Covered Product(s). Of the Focus Inquiries, the IRO shall select 40 of the Focus Inquiries that were Suspect Inquiries and 20 that were not Suspect Inquiries.

For each Inquiry reviewed, the IRO shall determine:

1. whether each item of information identified in Section III.B.2.e of the CIA is included in the Product Inquiries Database for each Inquiry reviewed by the IRO;

2. for each Sales Force Related non-Focus Inquiry reviewed by the IRO, whether the non-Focus Inquiry was categorized in accordance with Purdue's Policies and Procedures;

3. for each Suspect Inquiry for which the Compliance Officer conducted an Additional Compliance Review: (i) the basis for suspecting that improper promotion may have occurred; (ii) the steps undertaken as part of the Additional Compliance Review; (iii) the findings of the Compliance Officer as a result of the Additional Compliance Review; and (iv) any follow-up actions taken by Purdue based on the Compliance Officer's findings;

4. for each non-Suspect Focus Inquiry, the basis for identifying the Inquiry as non-Suspect and whether Purdue followed its policies in identifying the Inquiry as a non-Suspect Focus Inquiry; and

5. for each Inquiry reviewed by the IRO that was also reviewed by the Compliance Officer, whether the conclusions reached by the IRO and the Compliance Officer were consistent and, if not, the reasons for the discrepancies.

2. *Review of Purdue's Promotion Monitoring Program.*

As outlined in Section III.K of the CIA, Purdue has implemented a formalized process through which Purdue's District Managers evaluate and monitor sales representative interactions with HCPs (Promotion Monitoring Program). The District Managers record their observations on Promotion Monitoring Program Forms and provide copies of the forms to the Corporate Compliance Department for all situations in which the District Manager observes any sales representatives making potentially improper statements about any Purdue product(s). This indication of potentially improper statements may be made through the use of a rating of "1" (meaning not fully compliant) on the Promotion Monitoring Program Form (or an analogous indication on any successor rating system). Such a rating on the Promotion Monitoring Program Form indicates a potential compliance issue.

As set forth in Section III.K, if the Compliance Officer receives any Promotion Monitoring Program Forms indicating that a sales representative may have made improper statements about any Purdue product(s) (*e.g.*, a rating of "1" was indicated on the Promotion Monitoring Program Form), the Compliance Officer (or a designee) shall perform an additional review known as the "Compliance Detailing Review". Section III.K sets forth the requirements relating to the Compliance Detailing Review.

As part of each Promotional and Product Services Transactions Review, the IRO shall review a sample of the Promotion Monitoring Program Forms completed as part of Purdue's Promotion Monitoring Program and that relate to the Covered Product(s). Purdue shall provide to the IRO a list of employees (or unique employee identification numbers) and information about whether a Compliance Detailing Review was conducted with regard to each employee. The IRO shall randomly select 40 employees from the list for whom a Compliance Detailing Review was conducted and 10 employees for whom no Compliance Detailing Review was conducted. For each selected employee, Purdue shall provide the IRO with a list of all the Promotion Monitoring Program Forms

completed for the employee during the Reporting Period under review, and the IRO shall randomly select one Form for each employee.

For each Promotion Monitoring Program Form, the IRO shall determine whether:

a. each item of information identified in Section III.K of the CIA is included in each Promotion Monitoring Program Form reviewed;

b. a Compliance Detailing Review was conducted for each Program Monitoring Program Form containing an indication that a sales representative may have made improper statements about any Covered Product(s) (*e.g.*, a rating of "1" was indicated on the Promotion Monitoring Program Form); and

c. for each instance in which a Compliance Detailing Review was conducted: (i) the basis for suspecting that improper promotion may have occurred; (ii) the steps taken as part of the Compliance Detailing Review; (iii) the findings that resulted from the Compliance Detailing Review; and (iv) the follow-up action take as a result of the Compliance Detailing Review.

B. Promotional and Product Services Transactions Review Report

For each Reporting Period, the IRO shall prepare a Report based on its Promotional and Product Services Transactions Review. Each Report shall include the following:

1. *Elements to Be Included:*

a. Promotional and Product Services Transactions Review Objectives: A clear statement of the objectives intended to be achieved by the Review;

b. Engagement Protocol: A detailed narrative description of the procedures performed and a description of the universe of Inquiries from which samples were selected; and

c. Sources of Data: A full description of documentation (and/or other information) relied upon by the IRO when performing the Promotional and Product Services Transactions Review.

2. *Results to Be Included:*

The following results shall be included in each Promotional and Product Services Transactions Review Report:

a. a description of each type of sample unit reviewed, including the number of each type of sample reviewed (*i.e.*, Covered Product related Inquiries or Promotion Monitoring Program Forms) and an identification of the types of documents and information reviewed in association with each Inquiry and Promotion Monitoring Program Form;

b. for each Covered Product Inquiry sample unit, a summary of the information contained in the Product Inquiries Database about the Inquiry;

c. for each Inquiry sample unit reviewed, the IRO's findings and supporting rationale as to whether each item of information required by Section III.B.2.e of the CIA is included in the Product Inquiries Database;

d. for each Sales Force Related non-Focus Inquiry reviewed, whether the Inquiry was categorized in accordance with Purdue's Policies and Procedures;

e. for each Suspect Inquiry for which the Compliance Officer conducted an Additional Compliance Review, a summary of; (i) the basis for suspecting that improper promotion may have occurred; (ii) the steps undertaken as part of the Additional Compliance Review; (iii) the findings of the Compliance Officer as a result of the Additional Compliance Review; and (iv) any follow-up actions taken by Purdue as a result of the Compliance Officer's findings;

f. for each non-Suspect Focus Inquiry, a description of the rationale for identifying the Inquiry as non-Suspect, and a determination of whether Purdue followed its policies in identifying the Inquiry as a non-Suspect Focus Inquiry;

g. for each Inquiry reviewed by the IRO that was also reviewed by the Compliance Officer, a description of whether the conclusions reached by the IRO and the Compliance Officer were consistent and, if not, the reasons for the discrepancies;

h. for each Promotion Monitoring Program Form, a summary of the information contained in the form;

i. for each Promotion Monitoring Program Form, the IRO's findings and supporting rationale as to whether each item of information required by Section III.K of the CIA is included in the Promotion Monitoring Program Form. For any item listed in Section III.K that is not included on the form, an explanation of the reason for the omission;

j. a determination of whether a Compliance Detailing Review was conducted in connection with each Promotion Monitoring Program Form containing an indication that a Purdue sales representative may have made improper statements about any Covered Product(s) (*e.g.*, a rating of "1" was indicated on the Promotion Monitoring Program Form);

k. for each Promotion Monitoring Program Form for which a Compliance Detailing Review was completed, a summary of: (i) the basis for suspecting that improper promotion may have occurred; (ii) the steps taken as part of the Compliance Detailing Review; (iii) the findings that resulted from the Compliance Detailing Review; and (iv) the follow-up action taken as a result of the findings of the Compliance Detailing Review;

l. the IRO's findings and supporting rationale regarding any weaknesses in Purdue's systems, processes, policies, and practices relating to the Product Inquiries Database system and Focus Inquiry Reports, if any;

m. the IRO's findings and supporting rationale regarding any weaknesses in Purdue's systems, processes, policies, and practices relating to the Promotion Monitoring Program, if any;

n. the IRO's recommendations for improvement in Purdue's systems, processes, policies, and practices relating to the Product Inquiries Database and Focus Inquiry Reports, if any; and

o. the IRO's recommendations for improvement in Purdue's systems, processes, policies, and practices relating to the Promotion Monitoring Program, if any.